K011556

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In Accordance with SMDA of 1990

NOV 16 2001

MACS^{TL} HMA Anterior Spinal Stabilization System

May 16, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

CONTACT: Lisa M. Millington, Regulatory Associate
800-258-1946 (phone)
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lisa.millington@aesculap.com (email)

TRADE NAME: MACS^{TL} HMA Anterior Spinal Stabilization System

COMMON NAME: Anterior-Lateral Spinal Stabilization System

DEVICE CLASS: Class II

PRODUCT CODE: KWQ

CLASSIFICATION: 888.3060 – Spinal intervertebral body fixation orthosis

REVIEW PANEL: Orthopedic and Rehabilitation Devices Panel

INTENDED USE

This anterolateral/anterior system consists of several vertebral screws, locking nuts, spine plates and rods. The points of attachment are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T3-L5). This system is intended to provide stabilization during the development of a solid spinal fusion. When used as an anterolateral/anterior spine plate and rod system, the macs^{TL} HMA Anterior Spinal Stabilization System is indicated for patients with:

- Degenerative disk disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies
- Spondylolisthesis
- Spondylolysis
- Fracture
- Spinal stenosis
- Deformities (i.e., scoliosis, kyphosis, lordosis, whether neuromuscular or related to deficient posterior elements)
- Tumors (neoplastic disease)
- Pseudarthrosis
- Failed previous fusion surgery

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DEVICE DESCRIPTION

The MACS^{TL} HMA Anterior Spinal Stabilization System includes implantable metallic plates, rods, clamps, locking nuts and screws. The components are used in various combinations to form a construct for use during anterior spinal fusion surgery. The ***MACS^{TL} modular anterior construct system (K002824),*** which was cleared on May 8, 2001, consists of the twin screws, where as the MAC^{TL} HMA Anterior Spinal Stabilization System consists of the HMA Polyaxial and Monoaxial Screws. Both of these systems are considered a part of each other. The stabilization plates, connection rods, fixation nut, locking screw, bone graft clamp and screw have been cleared under the MACS^{TL} modular anterior construct system (K002824).

PERFORMANCE DATA

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. The new MACS^{TL} System conforms to applicable ASTM and ISO standards.

Fatigue testing of a "worst case" system configuration was conducted on samples of constructs made of titanium. A summary of this testing can be found in Section IV and the final reports are provided in Appendix I.

SUBSTANTIAL EQUIVALENCE

MACS^{TL} HMA Anterior Spinal Stabilization System is substantially equivalent in their intended use, design, and basic operating principles to the following predicate devices:

- **K-Centrum Anterior Spinal Fixation System**
  By The Spineology Group (#K990959 & K002371)
  The **K-Centrum® - Anterior Spinal Fixation System** is cleared for marketing. **K-Centrum®** is an anterior spinal construct made up of one rod connected to two cage-like vertebral body screws. This system was tested using ASTM F-1717-96 recommendations. Properties of stiffness, strength and fatigue life were determined. The **K-Centrum®** is intended to be used for the surgical treatment of vertebral body fractures and tumors. Equivalence can be seen in the design, material composition, surgical technique, testing methodologies and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Ms. Lisa M. Millington
Regulatory Associate
Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K011556
Trade/Device Name: MACS^{TL} HMA Anterior Spinal Stabilization System
Regulatory Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Fixation Orthosis
Regulatory Class: II
Product Code: KWQ
Dated: August 24, 2001
Received: August 29, 2001

Dear Ms. Millington:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

NOV 1 6 2001

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K011556

Device Name: MACS^{TL} HMA Anterior Spinal Stabilization System

Indication for Use:

This anterolateral / anterior system consists of several vertebral screws, locking nuts, spine plates and rods. The points of attachment are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T3-L5). This system is intended to provide stabilization during the development of a solid spinal fusion. When used as an anterolateral / anterior spine plate and rod system, the **macs^{TL}** HMA Anterior Spinal Stabilization System is indicated for patients with:

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- Pseudarthrosis
- Failed previous fusion surgery

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011556

Prescription Use X or Over-the-Counter Use _____

(per 21 CFR 801.109) (Optional Format 3-10-98)